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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,207	03/13/2007	Stefan Golz	004974.01212	2782
22907 7590 07/23/2008 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051				
EXAMINER				
CHEU, CHANGHWAI				
ART UNIT		PAPER NUMBER		
1641				
MAIL DATE		DELIVERY MODE		
07/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,207

Applicant(s)

GOLZ ET AL.

Examiner

JACOB CHEU

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-855)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 8/2/06

DETAILED ACTION

Status of Claims

With respect to Restriction Requirement, Applicant elected Group II, claim 2, without traverse filed on 6/13/08. Applicant also amended claims 4-11 depending on claim 2. Claims 1, 3, 12-26 have been cancelled. Accordingly, claims 2, 4-11 are under examination in this Application.

Claim Objections

1. Claim 4 is objected to because of the following informalities: it is suggested that Applicant recites "wherein the step of contacting is in a cell or at the surface of a cell".

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 2, 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: it is noted that the instant recited method directs to a screening assay for identifying potential therapeutics agents for treatment of certain diseases. The method suffers no control group been provided for comparison as to indicate which compound can be useful therapeutics. Although, the language recited "in the absence of said test compound" in step (i), there is no comparison with this "absence" of test compound because Applicant using "*or*" instead of "and" (emphasis added). Note, recitation of "or" is an optional step herein. Another drawback is that no step of increasing or decreasing of PRSC1 activity is linked to identification process for recognition which test compound is useful in treatment. Examiner suggests the term "modulate" which is disclosed by Applicant in the specification to mean increase or decrease activity for the claim.

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3. Claims 2, 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, step (i), it is not clear why Applicant recites "or" since there requires comparison of a control (i.e. absence of test compound) in the overall identification process (See preceding paragraph discussion of essential step).

With respect to claim 2, step (ii), it is not clear what is the purpose of determining the activity of said PRSC1 polypeptide at a different concentration of said test compound. Why these activities of PRSC1 at different concentration of the test compound have to do with the screening process? Are increased or decreased activity of the polypeptide are the indicators of screening process? Applicant needs to clarify.

With respect to claim 4, "the step of contacting" lacks antecedent basis.

With respect to claim 5, "the cells" lacks antecedent basis.

With respect to claim 6, "the step of contacting" lacks antecedent basis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Balasubramanian et al. (US 6140098) in view of Parce et al. (Science 1989, Vol. 246, page 243-247).

Balasubramanian et al. teach a method of screening useful therapeutics in treating immunological diseases (Col. 28, line 5-9; Col. 41, line 35-37). It is considered that some of the diseases in the recited method, such as cancer, inflammation, or endocrinological diseases, are associated with immunological dysfunction.

Balasubramanian et al. teach testing variety of drugs and identifying potential agonist or antagonist (i.e. increase or decrease *activity* of the target polypeptide) to a polypeptide (SEQ ID No. 4)(which has the same 433 amino acid residues as PRSC1 SEQ ID No. 2 in this application) (See Balasubramanian Col. 37, line 62 to Col. 38, line 40; Note, the protein AGP04, FDH02 or D1B2 all contain SEQ ID No. 4; Col. 18, line 8-12; Note, Although Balasubramanian et al. do not explicitly disclose determining target protein activity by using different concentration of potential drugs, nevertheless Balasubramanian et al. mentioned the Parce et al. reference in the same portion regarding for drug screening (Col. 38, line 34-36) where Parce et al teach determining target protein activity, e.g. acidification rate, with different concentrations of test compound, i.e. 2-5 μM of CCCP (carbonylcyanide chlorophenylhydrazone) compared with control medium (absence of test compound CCCP), in a dose-response experiment (See page 245, left column, third paragraph; Figure 3A).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Balasubramanian et al. to determine the activity of the particular polypeptide (PRSC1) in the absence and presence (including different concentrations) of the test compound(s), as taught by Parce et al. to screen useful potential drug(s) for treating the immunological abnormality associated with the PRSC1. One ordinary skill in the art would have been adopting or applying the dose-response method taught by Parce et al. since it is disclosed in the same portion within the Balasubramanian et al. reference concerning drug screening. This would also have reasonable expectation of success since the dose-response is well-known and widely practiced in the field, and it merely requires routine skill in the art.

With respect to claims 4-5, Balasubramanian et al. also teach using *in vitro* prokaryotic or eukaryotic cells as host expressing the SEQ ID No. 4 (PRSC1) polypeptide for drug screening (Col. 38, line 29-35).

With respect to claim 6, as discussed before, Balasubramanian et al. teach using protein alone, i.e. cell-free system, for drug screening. *supra*.

With respect to claim 7, Balasubramanian et al. teach labeling polypeptide for detection (Col. 40, line 42-46).

With respect to claim 8, Balasubramanian et al. teach labeling test compound for detection (Col. 39, line 48-50).

With respect to claim 9, Balasubramanian et al. teach using competitive immunoassay (displacement), such as ligand antibody displaced by the test compound for the target polypeptide (Col. 38, line 37-45; Col. 33, line 65 to Col. 34, line 10).

With respect to claim 10, Balasubramanian et al. teach immobilizing polypeptide to a solid support (Col. 41, line 10-15).

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al. in view of Parce et al. as applied to claim 2, and further in view of Fodor et al. (Science 1991 Vol. 251, page 767-773).
8. Balasubramanian et al. teach immobilizing polypeptide to a solid support for detection. Supra. However, none of Balasubramanian et al. or Parce et al. reference teaches alternatively immobilizing test compound on a solid support for detection.

Nonetheless, Balasubramanian et al. also mentioned Fodor et al. reference (in the same portion Balasubramanian et al. disclosing drug screening) where Fodor et al. teach immobilizing test compounds to a solid substrate for mass screening, i.e. tens of thousands of compounds (See Fodor et al. Abstract; Figure 1 and Figure 2; also Balasubramanian Col. 37, line 65 to Col. 38, line 9).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Balasubramanian and Parce et al. alternative detection method such as directly immobilizing test compound(s) to a solid support, as taught by Fodor et al. for screening useful treatment drugs associated with PRSC1. This would also have reasonable expectation of success since immobilizing test compound on a solid as an alternative to immobilizing polypeptide to a solid support is well-known and widely practiced in the art, and it merely requires routine skill in the art for performance.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/

Examiner, Art Unit 1641